Section 11 510(k) Device Summary

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AUG 22 2007

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K071648

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Establishment Registration Numbers	Registration Number 3003982601 Owner/Operator Number 9051098
Date of Preparation	May 22, 2007
Device Name	extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls
Common Name	Glycated Hemoglobin A1c Linearity Controls
Classification	21CFR 862.1660 Quality Control Material (assayed and unassayed)
Class	I
Product Code	JJX
Predicative Device	Company Name Bio-Rad Laboratories, Brand Name Lyphochek® Hemoglobin A1c Linearity Set Levels 1, 2, 3 and 4 510(k) Number K003030 Product Code GGM
Description of Device	The extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls comprises one vial each of 5 equally spaced levels of HbA1c control, 1 vial of reconstitution fluid and a product information sheet.

The product is provided in a lyophilized form and each vial is reconstituted with 0.25 mL of reconstitution fluid (0.09% sodium azide) prior to use.

Intended Use of Device

The extendSURE™ lyophilized hemoglobin A1c linearity controls are intended to verify the linearity of HbA1c assays across the patient reportable range (4 to 18%, NGSP aligned) using protocols established in individual laboratories.

The control is for *in vitro* diagnostic use only and should not be used past the expiry date.

Comparison with Predicate Device

The device (extendSURE™ lyophilized HbA1c Linearity Controls) shows substantial equivalence to device K003030 (BioRad Lyphochek® Hemoglobin A1c Linearity Set) in terms of intended use to verify the linearity of HbA1c assays across the patient reportable range using protocols established in individual laboratories. Both products are produced from human whole blood and are lyophilized for long term closed vial stability. Both cover a similar range of about 4 – 18% HbA1c (NGSP aligned).

The new devise (extendSURE™ Lyophilized HbA1c Linearity Controls) has 5 levels compared to the 4 in the predicate device.

Performance Characteristics

Stability studies at 2° to 8°C were performed on the Bayer DCA 2000 and the BioRad Variant Classic with the Hemoglobin A1c program. The results support a shelf life (closed vial) at 2° to 8°C of 36 months from the date of manufacture and an open vial (reconstituted) life of 7 days at 2° to 8°C.

The device is also suitable for use on the following Instruments; Olympus AU Series and Primus CLC 385.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Canterbury Scientific Ltd.
c/o Maurice Owen, Ph.D.
Scientific Director
14 Pope Street, Riccarton
Christchurch, Canterbury 8011
New Zealand

AUG 22 2007

Re: k071648
Trade/Device Name: extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls
Regulation Number: 21 CFR§862.1660
Regulation Name: Quality control material
Regulatory Class: Class I
Product Code: JJX
Dated: July 26, 2007
Received: July 30, 2007

Dear Dr. Owen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071648

Device Name: extendSURE™ Lyophilized Hemoglobin A1c Linearity Controls

Indications for Use: **For *in vitro* diagnostic use only**. The extendSURE™ lyophilized hemoglobin A1c linearity controls are intended to verify the linearity of HbA1c assays across the patient reportable range (4 to 18%, NGSP aligned) using protocols established in individual laboratories.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K071648